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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,521	05/18/2005	Michael R. Emmert-Buck	4239-73127-03	7250

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KLARQUIST SPARKMAN, LLP
121 S.W. SALMON STREET
SUITE #1600
PORTLAND, OR 97204-2988

EXAMINER	
CALAMITA, HEATHER	
ART UNIT	PAPER NUMBER
1637	
MAIL DATE	DELIVERY MODE
04/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/535,521	EMMERT-BUCK ET AL.	
	Examiner	Art Unit	
	HEATHER G. CALAMITA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 2, 3, 5-13 and 22-24* is/are pending in the application.

4a) Of the above claim(s) *8 and 22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 3, 5-7 and 9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 17, 2009, has been entered.

Status of Application, Amendments, and/or Claims

2. Amendments of February 17, 2009, have been received and entered in full. Claims 1-3, 5-13 and 22-24 are pending. Claims 8 and 22-24 are withdrawn as being directed to non-elected subject matter. Claims 1-7 and 9-14 are under examination. All arguments have been fully considered and thoroughly reviewed, but are deemed not persuasive for the reasons that follow. Any objections and rejections not reiterated below are hereby withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-7 and 9-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing because the second step reads, "sequestering molecules corresponding to a specific region or cell type of the tissue section in an aqueous solution contained within at least one of the plurality of grids or plurality of wells in the external inhibitor device, thereby preserving the 2-dimensional architecture of these molecules relative to other molecules present within the tissue section:

Therefore, this step deals with sequestering molecules alone. It is confusing as to how you can preserve the 2-D architecture if all that is required is putting molecules into wells.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-7 and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Kononen et al. (Nature Medicine, 1998).

With regard to claim 1, Kononen et al. teach a method for analyzing the transcriptome of a tissue section comprising analyzing two or more molecular species present in the tissue section while maintaining the 2-dimensional architecture of the molecules within the tissue section, wherein the method comprises (see Figure 1 and Legend):

treating the tissue section with an External Movement Inhibitor device having multiple discrete partitions, wherein the multiple discrete partitions comprise at least one of a plurality of grids or a plurality of wells (see Figure 1 and Legend)

sequestering molecules corresponding to a specific region or cell type of the tissue section in an aqueous solution contained within at least one of the plurality of grids or plurality of wells in the external inhibitor device, thereby preserving the 2-dimensional architecture of these molecules relative to other molecules present within the tissue section

manipulating molecules in the aqueous solution corresponding to a specific region or cell type of the tissue section while within the external movement inhibitor device (see Figure 1 and Legend, where the EMI is the adhesive-coated tape sectioning system which allows for transfer of the tissue sections to

the adhesive coated slide. This is set up in a grid pattern and the adhesive sequesters molecules corresponding to a specific region of the tissue section and preserves the 2-dimensional architecture of the molecules within the tissue section. The adhesive-coated slide also functions as an EMI as the adhesive on the slide performs the same function as the adhesive tape once the tissue is transferred to the slide because again the adhesive now forms a grid pattern which adheres the tissue to the slide. The tissue is then deparifinized and FISH or mRNA hybridization is performed, see p. 847 col. 1 *under Fluorescent in situ hybridization* and *mRNA in situ hybridization*. Here the molecule manipulation occurs during hybridization of the probes to the nucleic acids and the 2-D structure of the molecules, i.e. the sequences remain in tact. Finally, FISH or mRNA *in situ* hybridization is performed in an aqueous solution), and

determining the location (s) in the tissue section in which the two or more molecular species are present (see Figure 1 and Legend, where the EMI is the adhesive-coated tape sectioning system. This is set up in a grid pattern and the adhesive sequesters molecules corresponding to a specific region of the tissue section and preserves the 2-dimensional architecture of the molecules within the tissue section)

With regard to claim 2, Kononen et al. teach wherein tissue sample obtained from a mammal (see p.844 col. 2 first full paragraph where the tissues is from breast).

With regard to claim 3, Kononen et al. teach the mammal is a human (see the abstract and p.844 col. 2 first full paragraph where the tissues is from breasts of human patients).

With regard to claim 5, Kononen et al. teach the tissue sample is a section from a biopsy (see p. 844 col. 1 first paragraph of the introduction, where the tissue is a core tissue biopsy).

With regard to claim 6, Kononen et al. teach the molecular species are nucleic acid molecules (see the abstract where DNA and RNA targets are disclosed).

With regard to claim 7, Kononen et al. teach the method additionally comprises incubating the sequestered molecules under conditions sufficient to permit the manipulation of one or more preselected nucleic acid molecules if present in at least one of the plurality of grids or the plurality of wells, while

preserving the 2-dimensional architecture of said molecules relative to other molecules of the tissue section (see p. 845 col. 1, where the arrays were subjected to RNAish and see Figure 2 and Legend).

With regard to claim 9, Kononen et al. teach one or more of the preselected nucleic acid molecules are diagnostic of a disease state (see p. 845 col. 1, where the breast cancer array exhibited overexpression of ERBB2 mRNA).

With regard to claim 10, Kononen et al. teach the manipulation is assaying a biomolecule (see p. 845 col. 1, where the breast cancer array exhibited overexpression of ERBB2 mRNA and RNA is the biomolecule assayed).

With regard to claim 11, Kononen et al. teach incubating the sequestered molecules in the plurality of grids or the plurality of wells under conditions sufficient to permit the manipulation of said one or more preselected nucleic acid molecules (see p. 845 col. 1, where the arrays were subjected to RNAish and see Figure 2 and Legend).

With regard to claim 12, Kononen et al. teach the one or more preselected nucleic acid molecules are diagnostic of a disease state (see p. 845 col. 1, where the breast cancer array exhibited overexpression of ERBB2 mRNA).

With regard to claim 13, Kononen et al. teach the manipulation is assaying a biomolecule (see p. 845 col. 1, where the breast cancer array exhibited overexpression of ERBB2 mRNA and RNA is the biomolecule assayed).

Response to Arguments

5. Applicants' arguments filed February 17, 2009, have been fully considered but they are not persuasive.

Applicants argue with respect to the 102 rejection over Kononen et al., that Kononen et al. do not teach "sequestering molecules corresponding to a specific region or cell type of the tissue section in an aqueous solution contained within at least one of the plurality of grids or plurality of wells in

the external movement inhibitor device" or "manipulating molecules corresponding to a specific region or cell type of the tissue section in the aqueous solution while within the external movement device." This argument is not persuasive because as outlined in the rejection Kononen et al. teach these limitations. Additionally, the term manipulation is not specifically defined in the instant specification and therefore can be interpreted as simply hybridization of a probe to a molecule as disclosed by Kononen et al. Applicants argue that Kononen et al. require the tissue section be transferred from the adhesive coated tape sectioning system to a slide prior to the manipulation of the molecules and the manipulation does not occur while the sample is in the EMI. These arguments are not persuasive because Kononen et al. as discussed in the rejection above teaches an adhesive tape and an adhesive coated slide. Upon transfer of the tissue the adhesive coated slide functions as the EMI because the adhesive-coated slide also functions as an EMI as the adhesive on the slide performs the same function as the adhesive tape once the tissue is transferred to the slide because the adhesive now forms a grid pattern which adheres the tissue to the slide. thus meeting the limitations of the instant claim.

Summary

6. No claims were allowable.

Correspondence

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Heather G. Calamita whose telephone number is 571.272.2876 and whose e-mail address is heather.calamita@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner can normally be reached on Monday through Thursday, 7:00 AM to 5:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at 571.272.0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number 571.273.8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to 571.272.0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Heather G. Calamita, Ph.D./
Examiner, Art Unit 1637